UNITED ST[redacted]EPARTMENT OF COMMERCE
Patent and [redacted]ademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

V6

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/115,832	07/15/98	EBNER R	PF399

EXAMINER

022195
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

HM12/1208

DRAPER, G

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 12/08/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Election 7 9/20/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 17, 23-48, 19 is/are pending in the application.
Of the above, claim(s) 17, 19 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 23, 36, 40 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). (2)
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. **Part III: Detailed Office Action**

2. ***Restriction Requirement:***

Applicant's election with traverse of Group I, formerly claims 1-16, 20, 22 but are now represented by newly added claims 23-48 in Paper No. 10 of 9/20/99 is acknowledged. The traversal is on the ground(s) that the examiner has not shown a serious burden for restriction between each of the groups, although applicant's statement appears to concede that the three groups are patentably distinct.. This is not found persuasive because most contrary to applicants position, the written restriction clearly pointed out that there would be a serious burden on the examiner for both the search and examination of each group which are not classified in the same area and not required one for the other. Also argued is that a search for one groups would be overlapping and provide useful information about the other two groups. However, the fact that some useful information may be obtained in the searches of one group for that of another group, and the fact that their may possible be overlaps in the searches in not a sufficient basis for holding he restriction to be improper, because the search and examination of one groups many not yield all of the necessary information for the other groups.

The requirement is still deemed proper and is therefore made FINAL.

3. ***Formal Matters:***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

A title that is more specific to the elected group is suggested, such as "DNA ENCODING INTERLEUKIN-20"

4. ***Objections and 35 USC 112 Rejections:***

4a. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the subject matter which applicant regards as the invention.

The preamble of the claim refers to a composition, but only one element is recited. However, a composition should recite at least two elements. Therefore, it is suggested that the claims be amended to recite a carrier, or other auxiliary agent .

It is further pointed out that even though the preamble refers to a "composition", this claims is a substantial duplicate of claim 23 despite slight differences in the wording, and because it fails to further limit the invention of claims 23 (See MPEP 706.03 (k) and 2173.05 (o).

Claims 23(q) and 40 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite, ambiguous, confusing and/or are also non-enabling in referring to the complement of the polynucleotides of parts a, b, and c, because each of these part refer to a polynucleotide that is defined in terms of an encoded amino acids sequence, but the complement would not be expected to satisfy this limitation. Thus, it is unclear what the scope and/or intent of these claims are.

4b. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23(m) and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for how to make and use nucleic acids and nucleic acid fragments thereof , does not reasonably provide enablement for claims to nucleic acid sequences that encode for any fragment of the protein of Seq ID NO 2, and further in the absence of any recited activity . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use with a reasonable expectation of success the invention that is commensurate in scope with these claims.

This rejection is only being written because the claims are drafted in such a manner that they define the nucleic acid in terms of an encoded amino acid fragment. The claims are not

enabling for nucleic acids that would encode for **any** fragment of the protein. The specification makes general reference to fragments (from proteolytic cleavage or chemical synthesis); however, this does not serve to enable the scope of the claims. The only other teachings for the encoded protein other than the mature form of the protein is for the protein that has the N-terminal signal sequence. The skilled artisan would be faced with an undue amount of experimentation for determining how long the encoded fragment must be; from what portion of the protein the encoded fragment comes from or represent; does the encoded fragment have to correspond to a specific region on the encoded protein, and ensuring that the encoded fragment is biologically active. Furthermore, the skilled artisan would need to necessarily know how to make the specific encoded fragment with reasonable assurance that it possess the desired activity. Additionally, there are no structure/function studies provided for the encoded protein, thus, the skilled artisan does not know where the binding regions are; where the biologically active regions are and what specific activity these regions cover since many encoded protein possess multiple activities; nor is it known where the epitopic regions are; where the thermal, enzymatic or other stability regions are. All of these variables would have to be known for the skilled artisan to produce encoded fragments that possess the desired properties and to therefore be usable in a manner contemplated. But for those claims which state that the fragments have to possess a specific activity, the specification still does not provide enablement for such because the there are no teachings for what region of the encoded protein this activity corresponds to, and based on all of the other reasons set forth above the artisan would encounter undue experimentation in order to practice the scope of these claims.

It is also pointed out that the claims only require that the fragment has activity, but the claims fail to specifically state what the biological activity is (e.g. inflammatory activity, cytotoxic anti-HIV activity, chemotractant, etc), or the nature of the biological activity. But even if the claims did recite a more specific biological activity, there is still insufficient examples, evidence or guidance to support the breadth of the claims for such. Applicants have merely provided a definition for the encoded "fragment" and recited very general and non-specific way of obtaining

the fragments. Applicants have not taught whether the encoded fragment has to be biologically active and what activity it must possess (activity of the encoded protein, binding activity or antigenic activity or some other activity), nor has applicant taught what regions the fragment must cover or how long it should be. Also, the claims do not require that the fragment be a contiguous portion of the encoded protein. Again, in the absence of such, the skilled artisan would be faced with undue experimentation for trying to determiner how and where to start to make the full scope of the claims, because the enablement provisions of the statutes does not mean that specification merely refer to cleaving the protein from one or both ends in order to obtain a biologically protein fragment, but rather more is needed for all of the reasons stated above.

5. Prior Art Rejections:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 23 and 36 and 48 are rejected under 35 U.S.C. 102() as anticipated by or, in the alternative, under 35 U.S.C. 103(a) or (b) as obvious over any one of Hillier et al (AA443286, AA044549, w74664 OR w74558).

Each of the prior art disclose partial nucleic acid sequences that overlap with portions of the sequences of the claims for portions of the nucleic acid sequence or sequences that are sufficiently long and identical that they would satisfy the limitations of the claims for a nucleic acid that would encode for a fragment that is active. Despite the fact that the prior art does not refer to an encoded protein or portion or part of the protein, or fragment it would have been obvious that the nucleic acid sequences of the prior art would encode for a polypeptide fragments that has activity because of the identity in the sequences. Furthermore, the claims do not recite any property, function or specific biological activity for the encoded portions from these nucleic acid sequences, nor that the nucleic acid or the encoded fragment has to be of any specified length, thus the claims appear to be anticipated or in the alternative are prima facie obvious from these prior art sequences. .

6. Claims of the elected invention with the exception of claims 23(m) and 36 are free of the art, and all of the claims with the exception of claims 23(m) and 23 (q), and claims 36 and 40, appear to be in condition for allowance.

7. ***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.